



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0443; FRL-8850-02-OCSP]

Octamethylcyclotetra- siloxane (D4); Final Scope of the Risk Evaluation to be Conducted Under the Toxic Substances Control Act (TSCA); Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Toxic Substances Control Act (TSCA) and implementing regulations, EPA is announcing the availability of the final scope of the risk evaluation to be conducted for octamethylcyclotetra- siloxane (D4) (Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-; Chemical Abstracts Service Registry Number (CASRN) 556-67-2), a chemical substance for which EPA received a manufacturer request for risk evaluation. The scope document includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations that EPA plans to consider in conducting the risk evaluation for this chemical substance.

ADDRESSES: The docket, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0443, is available online at <https://www.regulations.gov> or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Bethany Masten, Existing Chemical Risk Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency (Mailcode 7404T), 1200 Pennsylvania Ave., NW,

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For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to entities that manufacture (including import) a chemical substance regulated under TSCA (*e.g.*, entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). The action may also be of interest to chemical processors, distributors in commerce, and users; non-governmental organizations in the environmental and public health sectors; state and local government agencies; and members of the public. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. What is the Agency's authority for taking this action?

The final scope document is issued pursuant to TSCA section 6(b)(4)(D) and TSCA implementing regulations at 40 CFR 702.41(c)(8).

C. What action is the Agency taking?

EPA is publishing the final scope of the risk evaluation for D4 under TSCA. Through the risk evaluation process, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, in accordance with TSCA section 6(b)(4).

II. Background

TSCA allows chemical manufacturers to request an EPA-conducted risk evaluation of a

chemical substance under 40 CFR 702.37. On March 19, 2020, EPA received a manufacturer request for a risk evaluation of D4 (Ref. 1). On June 17, 2020, EPA opened a 45-day public comment period to gather information relevant to the requested risk evaluation. EPA granted the request on October 6, 2020, and subsequently initiated the scoping process for the risk evaluation for this chemical substance. Pursuant to 40 CFR 702.41(c)(7), EPA announced the availability of and sought public comment on the draft scope document for the risk evaluation to be conducted for D4 under TSCA (86 FR 50347, September 8, 2021) (FRL-8850-01-OCSP) (Ref. 2).

The purpose of risk evaluation is to determine whether a chemical substance, or category of chemical substances, presents an unreasonable risk of injury to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation (15 U.S.C. 2605(b)(4)(A)). As part of this process, EPA must evaluate both hazards and exposures for the conditions of use; describe whether aggregate or sentinel exposures were considered and the basis for consideration; not consider costs or other nonrisk factors; take into account, where relevant, likely duration, intensity, frequency, and number of exposures and describe the weight of the scientific evidence for hazards and exposures (15 U.S.C. 2605(b)(4)(F)). This process will culminate in a determination of whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use (15 U.S.C. 2605(b)(4)(A); 40 CFR 702.47).

III. Information and Comments Received on the Draft Scope

In the *Federal Register* of September 8, 2021 (Ref. 2), EPA announced the availability of the draft scope document for the risk evaluation to be conducted for D4 under TSCA and invited public comments on EPA's draft scope document, including additional data or information relevant to the chemical substance or that otherwise could be useful to the Agency in finalizing the scope of the risk evaluation. To the extent that comments provided information on conditions of use, as well as other elements of the draft scope document, those comments and other submitted information (*e.g.*, relevant studies, assessments, information on degradation products,

and information on conditions of use) were used to inform revisions to the draft scope document and may be considered in subsequent phases of the risk evaluation process.

EPA received six unique submissions for D4, including comments from potentially affected businesses or trade associations, environmental and public health advocacy groups, and one member of the general public.

Comments addressed the overall approach to the risk evaluation process (*e.g.*, collection, consideration, and systematic review of relevant information), the specific elements of the scope document (*e.g.*, hazard, exposure, and potentially exposed or susceptible subpopulations), information specific to the chemical substance (*e.g.*, relevant studies, assessments, degradation products, and conditions of use), and topics beyond the draft scope document phase of the process (*e.g.*, risk management). EPA considered those comments, as applicable and appropriate, in developing the final scope document. Concurrently with the publication of the final scope document, EPA is publishing a response to comments document that contains a comprehensive summary of and response to public comments received on the D4 draft scope document. The

comprehensive response to comments document is available in the docket EPA-HQ-OPPT-2018-0443 (Ref. 3).

IV. References

The following is a listing of the documents that are specifically referenced in this *Federal Register* notice. The docket for this action includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket. For assistance in locating these referenced documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Octamethylcyclotetra-Siloxane (D4); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments. *Federal Register*. (85 FR 36586, June 17, 2020) (FRL-10010-49).

2. EPA. Octamethylcyclotetra-Siloxane (D4); Draft Scope of the Risk Evaluation to be Conducted Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments. *Federal Register*. (86 FR 50347, September 8, 2021) (FRL-8850-01-OCSPP).

3. EPA. EPA Response to Public Comments Received on the Draft Scope of the Risk Evaluation for Under the Toxic Substances Control Act (TSCA) for Octamethylcyclotetra-siloxane (Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-) (D4) CASRN 556-67-2 (March 2022).

Authority: 15 U.S.C. 2601 *et seq.*

Michael S. Regan,

Administrator.

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